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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,399	04/03/2001	Kevin X. Chen	IN01154K	1622

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/12/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,399

Applicant(s)

CHEN ET AL.

Examiner

Robert B Mondesi

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-33 and 36 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-10, 12, 26, 29 and 34 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 11, 13-25, 27, 28, 30 and 35 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-27, 31,32 and 33-36 drawn to macrocyclic compounds and pharmaceutical compounds, classified in Class 514 subclass 009
 - II. Claims 28-30, drawn to a process of use or method of treatment, classified in Class 424, subclass 9.322.
2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case : product can be used in the alternative processes of apoptosis of cells.
3. This application contains claims directed to the following patentably distinct compounds of the claimed invention: In claims, 1-27 and 36 the presence of a compound general structure formula (Formula 1) and the ability to substitute a variety of independently selected moieties in positions X, Y, R1, R2, R3 and R4 has given rise to a multitude of macrocyclic compounds. Each one of these compounds is patentably distinct absent factual evidence to the contrary. Furthermore in claim 1, the presence of a general compound formula (Formula 1) and the ability to substitute different atoms or molecules in positions A, E, G, J, L, M and Q has also given rise to a multitude of macrocyclic compounds. Each

Art Unit: 1653

one of these compounds is also patentably distinct absent factual evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed moiety in positions X, Y, R1, R2, R3 and R4 that is searchable for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the moieties selected in positions X, Y, R1, R2, R3 and R4 in the general formula (Formula I) are set forth in a series of alternatives.

Applicant is also required to elect a single disclosed molecule or atom in positions A, E, G, J, L, M and Q. Currently, the atoms or molecules selected in positions A, E, G, J, L, M, and Q the general formula (Formula I) are set forth in a series of alternatives.

Applicant is advised that a reply to this requirement must include a single moiety in positions X, Y, R1, R2, R3, and R4 and a single atom or molecule in positions A, E, G, J, L, M and Q that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1653

This application contains claims directed to the following patentably distinct compounds of the claimed invention: In claims 31-35 a multitude of macrocyclic compounds are presented. Each one of these compounds exhibits different biological properties, for example some of the macrocyclic compounds can be proton donors involved in acid base reactions and some of the other macrocyclic compounds can participate more readily in a SN1 type reaction. Each one of these compounds is patentably distinct absent factual evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single macrocyclic compound from the group of compounds presented in claim 31.

Applicant is advised that a reply to this requirement must include a single macrocyclic compound from the list of compounds that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different

Art Unit: 1653

classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

During a telephone conversation with Mr. Palaiyur Kalyonarman on 07-07-03 a provisional election was made with traverse to prosecute the invention of group I, Claims 1-27, 31,32 and 33-36 drawn to macrocyclic compounds exemplified by compound on page 385 (third compound from the top of the page). This compound was determined by the applicant to be representative of the core structure of the invention. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-30 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

RBM 7-07-03

Election/Restrictions

Applicant's election of Invention I, Claims 1-27, 31,32 and 33-36 during a telephone conversation on 07-07-03 is acknowledged. The applicant elected a representative core structure of this invention. This core structure can be found on page 385 (third compound from the top of the page). After a compound search of the elected core structure and its closely related structures, the compound representing the core structure is found to be free of prior art and hence novel. Therefore all other compounds representing obvious variants of the claimed invention are rejoined. Claims 28-30 pertaining to invention in Group II are also rejoined per *In re Ochiai*, 71F.3d 1565, 37USPQ 1127 (Fed Cir. 1995).

Priority

1. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Information Disclosure Statement

2. The IDS filed 04/03/2001 has been received, entered and considered. A signed copy of PTO-1449 for this IDS is attached.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 6, 8-10, 12, 26, 29 and 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 objected to because of the following informalities: The word "or" missing in line 7 on page 3. Failure to provide the word, "or", implies that all the molecules and atoms that are suggested are being simultaneously substituted in position R₅. There is an extra "or" in line 4 on page 367. Appropriate correction is required.
4. Claim 2 is rejected because the word "or" is missing before the final structure.
5. Claim 3 is rejected because the verb "is" appears twice in the sentence and the word "or" is missing before the final structure.
6. Claim 4 is rejected because the word "or" is missing before the final structure. Failure to provide the word, "or", implies that all the molecules and atoms that are suggested are being simultaneously substituted in position R₁₀.

Art Unit: 1653

7. Claim 6 is rejected to because the word "or" is missing before the final structure. Failure to provide the word , "or", implies that all the molecules and atoms that are suggested are being simultaneously substituted in position R₂ .
8. Claim 8 is rejected because the word "or" is missing before the final structure. Failure to provide the word , "or", implies that all the molecules and atoms that are suggested are being simultaneously substituted in position R₁ .
9. Claims 9, 10 and 12 are rejected because there needs to be a period at the end of the sentence. Without out a period the sentence is not complete and one assumes that there is more wording in the claim.
10. Claim 34 is rejected because its not clear what is meant by the phrase, "still additionally".

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 26 and 29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

Claims 5, 7, 11, 13-25, 27, 28, 30, 35 are objected to as being dependent upon a rejected base claim.

Allowable Subject Matter

12. 31-33, and 36 are allowed.

13. The following is an examiner's statement of reasons for allowance:

14. After a compound search of the elected core structure and its closely related structures, the compound representing the core structure is found to be free of prior art and hence novel. A text search of key words; macrocyclic compounds; serine protease inhibitors, and Hepatitis C was also performed confirming the novelty of the said compound core structure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm.

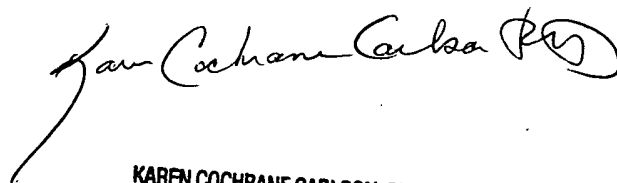
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

• Application/Control Number: 09/825,399
Art Unit: 1653

Page 10

Any inquiry of a general nature or relating to the status of this application
or proceeding should be directed to the receptionist whose telephone number is
703-308-0198.

RBM
August 11, 2003

A handwritten signature in cursive script, reading "Karen Cochrane Carlson" followed by a circled "PC".

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER